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10/537,197

06/14/2007

David Strand

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EXAMINER

DINH, BACH T

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,197	<b>Applicant(s)</b> STRAND ET AL.	
	<b>Examiner</b> BACH T. DINH	<b>Art Unit</b> 1795	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) 21-56 and 71-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 57-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/09/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

1. This is the response to the communication filed on 03/21/2011.
2. Claims 1-86 are current pending.
3. Claims 21-56 and 71-86 are withdrawn from consideration.
4. Claims 1-20, 57-69 and 70 have been fully considered.

### ***Election/Restrictions***

5. Applicant's election with traverse of election restriction requirement mailed on 02/17/2011 in the reply filed on 03/21/2011 is acknowledged. The traversal is on the ground(s) that "Applicants believe the subject matter of the elected group A can be effectively and efficiently examined in this application, together with the Group B claims". This is not found persuasive because as stated in the restriction requirement mailed on 02/17/2011, the restriction is proper as the common technical feature between groups A and B is taught by the prior art.

The requirement is still deemed proper and is therefore made FINAL.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

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application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-20 and 57-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 and 24 of copending Application No. 10/542,509. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-17 and 24 copending Application No. 10/542,509 recite a separation chamber having an inlet port and an outlet port, a separation chamber (claim 1), an electrode chamber with electrodes positioned therein (claims 1 and 3) and the electrode chamber has non-uniform configuration (claim 4).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 17-18, 57-58, 62-65 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Hurd (US 4,732,656).

Addressing claims 1, 57 and 70, Hurd discloses an electrophoretic device (figures 6-7) and a method for focusing a charged analyte, comprising:

A separation chamber 20 having a fluid inlet 27 and a fluid outlet port (col. 5 lines 45-51, collecting tubes), with a flow path from the fluid inlet port to the fluid outlet port defining a fluid flow direction through the separation chamber (5:36-6:5);

An electrode chamber 10 separated from the separation chamber 20 by a porous, conductive membrane (5:37-43 and 3:2-7, dialysis membrane that allows electric field lines to pass freely through); and

Electrodes (32 and 33) positioned in the electrode chamber 10 and operative when energized to generate an electrical field gradient in the separation chamber (2:46-59),

Wherein the electrode chamber has a non-uniform configuration along at least a portion of the flow path of the separation chamber (figures 6-7).

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Introducing a fluid sample comprising an analyte into the separation chamber via the inlet port (5:13-15); and

Energizing the electrodes to establish an electric field gradient in the separation chamber to focus at least a portion of the analyte at a location along the flow path (5:64-6:5).

Addressing claim 2, please see figures 6-7.

Addressing claim 3, please see figures 6-7.

Addressing claim 17, electrodes 32 and 33 are located proximate the ends of the electrode chamber.

Addressing claim 18, as stated above, the electric field is affected by the cross-sectional area of the electrode chamber, in figure 7, the electrode chamber of Hurd comprises two linear segments having different slopes; thus, the electric field in the electrode chamber of figure 7 also has two linear segments having different slopes.

Addressing claim 58, because the shape of the electrode chamber varies as seen in figures 6-7, the electric field gradient is also changed during the course of focusing the analyte.

Addressing claims 62-65, please see 6:39-48.

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10. Claim 68 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hurd (US 4,732,656).

Addressing claim 68, Hurd does not disclose nor suggest that the electrophoretic device is disposed after a single use; therefore, when the electrophoretic device is used again after the first separation is completed, the introduction of the fluid comprises the charged analyte of the subsequent run satisfy the claimed limitation of "additional fluid comprising charged analyte is introduced into the separation chamber and focused".

In the alternative, at the time of the invention, one with ordinary skill in the art would have found it obvious to modify the method of Hurd by introducing additional fluid comprising charged analyte into the separation chamber and focused after the first run is completed because doing so would allow one to separate and focus more analyte using the same electrophoretic device.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
13. Claims 4-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurd (US 4,732,656).

Addressing claims 4-8 and 10-12, Hurd discloses the electrode chamber has side walls and top wall (figures 5-6).

Hurd is silent regarding the required geometries of current claims. However, it is noted from the originally filed specification that there are little criticality regarding whether the electrode chamber has a substantially uniform width and a non-uniform height as recited in claim 4 or the electrode chamber has a non-uniform width and a non-uniform height as required in claim 5. In other words, the geometries of the electrode chamber recited in claims 4-8 and 10-12 are for providing the non-uniform cross-sectional area of the electrode chamber in order to induce or effectively causes or alters the gradient effect in the electric field (please see paragraph 74 on pages 16-17 of the originally filed specification) without any disclosure from the originally filed specification regarding one geometry as being superior in inducing, causing or altering the gradient effect in the electric field.

As stated above, Hurd discloses the electrode chamber with non-uniform cross sectional area for the same purpose of inducing, causing or altering the gradient effect in the electric field as that of current application.

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the shape or geometry of the electrode chamber of Hurd because the configurations of the claimed electrode chamber is a matter of choice which a person of



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ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant (please see MPEP 2144.04, section IV(b)). Thus, absent contrary evidence to show the criticality of the recited geometries besides for the purpose of inducing, causing or altering the gradient effect in the electric field, which is disclosed by Hurd, one of ordinary skill in the art would have arrived at the claimed geometries when performing routine experiment with the shape of the electrode chamber in order to induce, cause or alter the gradient effect in the electric field.

14. Claims 9, 13-14, 19, 59-61, 66 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurd (US 4,732,656) in view of Ivory et al. (US 6,277,258).

Addressing claims 9, 13-14 and 60-61, Hurd is silent regarding molecular sieve in the separation chamber.

Ivory discloses an electrophoretic device for focusing DNA, RNA and proteins; wherein, the separation chamber comprises molecular sieve (6:30-44) such as organic gels, inorganic gels and soluble gels (6:30-44 and Table 4).

At the time of the invention, one of ordinary skill in the art would have found it obvious to modify the separation chamber of Hurd with the molecular sieve disclosed by Ivory because the molecular sieve reduces dispersion (16:29-30) as well as increasing resolution (17:45-46).

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Addressing claims 59 and 66, Hurd is silent regarding the charged analyte comprises an uncharged material sorbed to or otherwise associated with a charged carrier.

Ivory discloses a method for focusing biological analytes comprises the step of focusing uncharged materials sorbed into charged carriers such as micelles and liposomes or the detergent (6:61-67).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the method of Hurd for focusing the uncharged materials sorbed into charged carriers such as micelles and liposomes or the detergent as disclosed by Ivory because the device of Hurd is capable of focusing charged analytes as stated above; thus, the device is capable of focusing the uncharged materials sorbed into charged carriers such as micelles and liposomes or the detergent (Ivory, 6:61-67). Therefore, such modification would broaden utility of the device of Hurd for focusing other analytes.

Addressing claims 19 and 69, in figure 5, Hurd discloses the electrode chamber comprises four electrodes (figure 5, a plurality of electrode pairs 22).

Hurd is silent regarding the electrode chamber of figures 5-6 comprises four electrodes and the electric field gradient is dynamically controlled.

Ivory discloses the electric field gradient is dynamically controlled (5:15-29) with 50 electrodes (5:62-67).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the electrode chamber and the method of Hurd with the plurality of electrodes and the step of dynamically controlling the electric field gradient as disclosed

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by Ivory because adjusting the electric field gradient during a run improves the resolution of the components (5:26-29) and the plurality of electrodes allow the adjustment of the electric field gradient.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurd (US 4,732,656) in view of Ivory et al. (US 6,277,258) as applied to claims 9, 13-14, 59-61, 66 and 69 above, and further in view of Menchen et al. (US 5,759,369).

Addressing claim 15, Ivory is silent regarding the molecular weight of the gel.

Menchen discloses a viscous polymer medium for use in electrophoresis; wherein the molecular weight is between 4 to about 500 kilodaltons (9:62-67), which encompasses the claimed range.

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the gel of Hurd in view of Ivory with the viscous polymer medium of Menchen because the polymer of Menchen provides high resolution separation of polynucleotides (Menchen, Abstract).

16. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurd (US 4,732,656) in view of Ivory et al. (US 6,277,258) as applied to claims 9, 13-14, 59-61, 66 and 69 above, and further in view of Wilson et al. (US 5,019,232).

Addressing claim 16, Ivory is silent regarding the molecular sieve comprises zeolites.

Wilson discloses a medium for electrophoresis comprises zeolites (6:1-10).

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At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the molecular sieve of Hurd in view of Ivory with zeolites material as disclosed by Wilson because the zeolites material provides processing aid or excipient (Wilson, 6:1-10).

17. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurd (US 4,732,656) in view of Hausfeld (US 4,401,538).

Addressing claim 20, Hurd is silent regarding the separation chamber has a substantially uniform height and a non-uniform width or a substantially uniform width and a non-uniform height or a non-uniform width and a non-uniform height. However, it is noted from the originally filed specification that that there are little criticality regarding whether the electrode chamber has a substantially uniform width and a non-uniform height or a substantially uniform width and a non-uniform height or a non-uniform width and a non-uniform height. In other words, the recited geometries are for varying the cross-sectional area of the separation chamber to induce or cause a gradient effect in the electric field (paragraph 73 on pages 15-16).

Hausfeld discloses an electrophoresis device comprises the separation chamber 80a and electrode chamber 80b having non-uniform cross-sectional area (figures 5 and 7). In figures 3-5 and 7, the separation chamber 33, 70a and 80a, respectively, has a non-uniform width and non-uniform height.

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the separation chamber of Hurd to have a non-uniform height and a

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non-uniform width as disclosed by Hausfeld because combining the separation chamber of non-uniform height and non-uniform width of Hausfeld with the electrode chamber having non-uniform cross-sectional area of Hurd as disclosed by Hausfeld (figures 3-5 and 7) to obtain the predictable result of adjusting the electric field gradient for electrophoretic separation is a matter of obviousness (Rationale A, KSR decision, MPEP 2141). Furthermore, the simple substitution of the uniform cross-sectional area separation chamber of Hurd with the separation chamber of non-uniform height and non-uniform width of Hausfeld to obtain the predictable result of adjusting the electric field gradient for electrophoretic separation is a matter of obviousness (Rationale B, KSR decision, MPEP 2141).

18. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hurd (US 4,732,656) in view of Ivory et al. (US 6,277,258) as applied to claims 9, 13-14, 59-61, 66 and 69 above, and further in view of Karger et al. (US 5,084,150).

Addressing claim 67, Hurd and Ivory are silent regard the micelles are SDS.

Karger discloses a method of electrophoretic separation; wherein, uncharged particles are sorbed onto charged micelles such as SDS for separation (1:59-2:10).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the micelles of Hurd in view of Ivory with the charged SDS micelles because the simple substitution of the micelles of Ivory for the charged SDS micelles of Karger to obtain the predictable result of electrophoretically separating uncharged

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particles is a matter of obviousness (Karger, 1:59-2:10, Rationale B, KSR decision, MPEP 2141).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BACH T. DINH whose telephone number is (571)270-5118. The examiner can normally be reached on Monday-Friday EST 7:00 A.M-3:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571)272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BD

05/06/2011

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1724